

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2016.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-592

Trade Name: Amoxicillin Trihydrate and Clavulanate Potassium Tablets
Pioneer: CLAVAMOX®
Ingredients: Amoxicillin trihydrate and clavulanate potassium
Sponsor: Putney, Inc.
Approval Date: September 8, 2016
Status: Rx
Route: Oral
Species: Dogs and cats
Drug Form: Tablet
Concentration: 62.5 mg (50 mg amoxicillin, 12.5 mg clavulanic acid)
125 mg (100 mg amoxicillin, 25 mg clavulanic acid)
250 mg (200 mg amoxicillin, 50 mg clavulanic acid)
375 mg (300 mg amoxicillin, 75 mg clavulanic acid)
Indications: Dogs: For the treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β -lactamase-producing *Staphylococcus aureus*, non- β -lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. Amoxicillin trihydrate and clavulanate potassium tablets have been shown to be clinically effective for treating cases of canine periodontal disease.
Cats: For the treatment of skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: β -lactamase-producing *Staphylococcus aureus*, non- β -lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Sponsor Change

NADA Numbers: 099-667, 110-399

Previous Sponsor: Sogeval S.A.
New Sponsor: Ceva Sante Animale
Drug Labeler Code: 013744

Withdrawal of Approval

NADA Number: 012-548

Sponsor: Elanco US, Inc.
Trade Name: Tylosin® plus Hygromix
Ingredients: Tylosin phosphate and hygromycin B

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.274

NADA Number: 013-162

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Sponsor: Elanco US, Inc.
Trade Name: Tylan® Premix No.10
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.625

NADA Number: 013-388

Sponsor: Elanco US, Inc.
Trade Name: Hygromix-Tylan® Premix
Ingredients: Hygromycin B and tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.274

NADA Number: 015-166

Sponsor: Elanco US, Inc.
Trade Name: Tylan® 100 Premix
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.625

NADA Number: 127-507

Sponsor: Elanco US, Inc.
Trade Name: Tylan® 5 Sulfa-G, Tylan® 10 Sulfa-G, Tylan® 20 Sulfa-G, Tylan® 40 Sulfa-G
Ingredients: Tylosin phosphate and sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.630

NADA Number: 141-164

Sponsor: Elanco US, Inc.
Trade Name: Coban® plus Tylan®
Ingredients: Monensin and tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.355

NADA Number: 141-170

Sponsor: Elanco US, Inc.
Trade Name: Monteban® plus Tylan®
Ingredients: Narasin and tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.363

NADA Number: 141-198

Sponsor: Elanco US, Inc.
Trade Name: Tylan® plus Bio-Cox®
Ingredients: Tylosin phosphate and salinomycin

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This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.550

Suitability Petitions

Number: 16-P-1991

Petitioner:	Felix Pharmaceuticals Pvt. Ltd.
Date Filed:	July 12, 2016
Action:	Approved
Action Date:	September 21, 2016
Description:	The petitioner requested to file an ANADA for a generic carprofen tablet for use in dogs that differs from the pioneer product, Rimadyl® (carprofen) chewable tablet, sponsored by Zoetis Inc. under 141-111. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.